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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,653	08/05/2003	Randall Lashinski	MITRAL.1CP3C2	6365

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,653	LASHINSKI ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04; 4/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Preliminary Amendment filed 5/20/04 has been entered. The changes to the specification have been approved by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: the first sentence of the specification regarding priority must be updated to include the most current status of each application. Application 09/774,869 is now U.S. Patent No. 6,537,314 and application 09/968,272 is now U.S. Patent No. 6,709,456. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731, as cited in applicant's IDS) in view of Alferness et al. (USPAP 2003/0105520, as cited in applicant's IDS).

Vidlund et al. discloses a system for remodeling a mitral valve annulus with all the elements of claim 1, but is silent to a control on the catheter for reversibly transforming the

implant between the first flexible configuration and the second remodeling configuration. See paragraph [0125] for a delivery catheter, and paragraph [0124] for an implant (110h) that is reversibly movable between a first, flexible configuration (Figure 4h) for delivery to a site adjacent the annulus of the mitral valve, and a second configuration (Figure 4i) for remodeling the mitral valve annulus. When the wire actuation mechanism (90) is pulled proximally, the distal end of the implant (110h) retracts, the implant changes shape to the second remodeling configuration, and the implant becomes rigid due to the tension created in the wire. Because the implant (110h) is implanted into the coronary sinus using catheter-based delivery techniques, it is clearly implied that the implant is detachably carried by the delivery catheter in some way. Alferness et al. teaches a system for effecting the mitral valve annulus geometry wherein an implant (30) is detachably carried by a delivery catheter (52) having a lumen (54) by being slidably received in the lumen (54). The implant (30) includes first anchor (32), second anchor (36) and a cable (34). The cable (34) has a coupling (38) that is coupled to the coupling (40) of a tension cable (42) disposed within the delivery catheter (52). When the tension cable (42) is pulled proximally, tension is applied to the cable (34) and the geometry of the mitral valve annulus is effected. A lock (44) on the second anchor (36) maintains the tension in the cable (34) while allowing the catheter (52) and tension cable (42) with coupling (40) to be removed to complete the deployment process. See Figures 2-5 and paragraphs [0034], [0038], [0040] and [0041]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness et al. to modify the system of Vidlund et al. such that the implant is deployed into the coronary sinus using a similar technique. By including a coupling to the actuation mechanism (90) and a lock to the proximal end of the implant (110h), a

control on the catheter in the form of a tension cable with coupling can be used to reversibly transform the implant between the first flexible configuration and the second remodeling configuration by creating or releasing tension in the actuation mechanism (90) prior to locking. The implant (110h) can be maintained in the second remodeling configuration by the lock while the delivery catheter (52) and control can be removed.

Claim 2, see Figure 4i for the implant comprising an arc when in the remodeling configuration.

With respect to claim 3, Vidlund et al. does not expressly disclose that a best-fit constant radius curve corresponding to the arc has a radius within the range of from about 10mm to 20mm. However, according to Figure 4i and paragraph [0125] the arc of the implant (110h) of Vidlund et al. in the second remodeling configuration will have a radius sized to remodel the mitral valve annulus. Because the arc of the implant of applicant has a radius between 10-20mm in order to remodel the mitral valve annulus, it is obvious that the arc radius of Vidlund et al. will also fall within the required range of claim 3.

Claims 7 and 8, see paragraph [0124] for the system further including an anchor provided on the distal end (distal extension) of the implant.

With respect to claims 9-11, Vidlund et al. does not expressly disclose the embodiment shown in Figures 4h-4i as including an anchor in the form of a barb for piercing the wall of the vessel. Vidlund et al. does, however, disclose a body (110c) including barbs (111) in the embodiment shown in Figure 4c in order to engage with the vessel wall for maintaining the position of the body (110c) within the vessel. See Figure 4c and paragraph [0119]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make

the distal anchor assembly of the embodiment shown in Figures 4h-4i in the form of a barb (claim 10) as well as include barbs along the length of the implant (110h) in order to engage and pierce the vessel wall to maintain the position of the body (110h) within the coronary sinus. Barbs by nature provide as a friction enhancing surface structure (claim 9). When applied to the implant (110h), the barbs will be moveable with the implant (110h) between an axial orientation (Figure 4h) and an inclined orientation achieved when the implant is in the second remodeling configuration (Figure 4i).

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. and Alferness et al. as applied to claim 2 above, and further in view of Adams et al. (USPAP 2003/0083538, as cited in applicant's IDS).

Vidlund et al., as modified by Alferness et al., discloses a system for remodeling a mitral valve annulus with all the elements of claim 2, but is silent to the implant comprising a compound curve when in the remodeling configuration, as required by claim 4. See paragraph [0124] for the elongated body (110h) having a final shape with an increased radius of curvature in some regions and a decreased radius of curvature in other regions. Adams et al. teaches a device (50) having a "w" configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion (23) of the atrial wall (21) of the coronary sinus (14) in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. See Figure 3 and paragraph [0051]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the implant (110h) has a compound curve, and specifically

comprises a "w" configuration (claim 5). This shape will apply a force to a discrete portion of the atrial wall of the coronary sinus to reshape the mitral valve annulus in treating dilated cardiomyopathy.

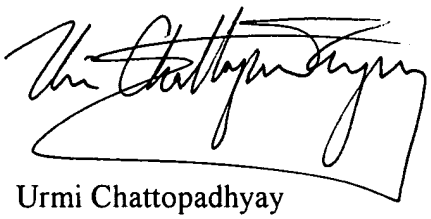
6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vidlund et al. and Alferness et al. as applied to claim 1 above, and further in view of Solem et al. (USPN 6,210,432, as cited in applicant's IDS).

Vidlund et al., as modified by Alferness et al., discloses a system for remodeling a mitral valve annulus with all the elements of claim 1, but is silent to the device further comprising a coating on the implant, as required by claim 6. Solem et al. teaches a device for the treatment of mitral insufficiency, wherein the device is coated with heparin in order to avoid thrombosis in the coronary sinus, thus reducing the need for aspirin, ticlopedine or anticoagulant therapy. See column 5, lines 14-17. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solem et al. to modify the implant of Vidlund et al. by including a coating of heparin on the implant (110h) in order to avoid thrombosis in the coronary sinus, thus reducing the need for aspirin, ticlopedine or anticoagulant therapy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738